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09/807,657	04/16/2001	Nathalie Garcon	B 45158	2235

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,657

Applicant(s)

GARCON, NATHALIE

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-37, 39-62, 71-116 and 118-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-37, 39, 40, 42, 44-62, 115, 116, 118, and 119 is/are allowed.
- 6) ☒ Claim(s) 41, 43, 71-81 and 93-114 is/are rejected.
- 7) ☒ Claim(s) 82-92 and 120-125 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 32-37, 39-62, 71-116, and 118-125 are currently pending in the present application. In the prior action, mailed on September 23, 2003, claims 32-37, 42, 44-62, 115, 116, and 118 were indicated as allowable, and claims 39-41, 43, 71-114, and 119 were rejected. In the Response submitted on January 20, 2004, the Applicant amended claims 39-41, 43, 71-81, and 119; and added new claims 120-125.

Specification

2. **(Prior Objection-Maintained)** The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. The specification does not provide any antecedent basis for the claim limitation regarding immunostimulants "wherein the immunostimulant is not a saponin derived from the bark of Quillaja Saponaria Molina." Note- this is not a lack of written description support rejection. It is required however, that the description of the application provide antecedent basis for claim language. See, 37 CFR 1.75 (d) (1) and MPEP 608.01 (o). It is suggested that a sentence such as the following be inserted at the end of the last paragraph of page 5: -- The immunostimulants of the vaccines of the present invention may be any immunostimulant, including those listed above, or may be any immunostimulant wherein the immunostimulant is not a saponin derived from the bark of Quillaja Saponaria Molina. -- Such an insertion would overcome the present objection.

The Applicant traverses the objection on the grounds that the specification provides written description support for the claimed invention. However, as was indicated in the prior action, this is not a rejection for lack of written description. Further, there is no requirement being made for the Applicant to disclaim any inventions. However, the Applicant is claiming a specific genera of inventions, those wherein the immunostimulant is other than a saponin. What is being required is a reference in the specification to this claimed genus such that it provides antecedent basis for the claim limitation.

3. **(Prior Objection-Withdrawn)** The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not appear to contain antecedent basis for the claim language identifying LnRH(GnRH) as an antigen. In view of the amendment of the specification, the objection is withdrawn.

4. **(Prior Objection-Withdrawn)** The disclosure was objected to because of the following informalities: on page 9, the application refers to vaccines comprising the component Hib by its acronym, but does first not identify the vaccine component by its full name (Haemophilus influenzae b). In view of the amendment of the specification (page 9, line 11), the objection is withdrawn.

5. **(New Objection)** The disclosure is objected to because of the following informalities: The Applicant indicates on page 21 of the Response that the RTS, S antigen includes both the CS protein of P. falciparum and the S antigen of hepatitis B. Substantially the same language is used on page 12, lines 11-28 of the application. However, in view of the Applicant's comments in the

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Response, it appears that the term "RTS" on line 13 of page twelve should instead read - -

RTS,S- -. Appropriate correction is required.

Claim Objections

6. **(Prior Objection- Withdrawn in part)** Claims 71-81 were objected to because of the following informalities: These claims each identify Hib and LnRH(GnRH) as antigens that may be used in the claimed invention. In view of the amendment of the claim to provide the full name of the Hib antigen, the objection is withdrawn in part. However, the objection is maintained because the claims still refer to LnRH(GnRH) only by its acronym.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection-Maintained)** Claims 41, 43, 71-81, and 93-114 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for vaccines against all of the identified pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The Applicant argues that the amendments made to the claims (i.e. insertion of the phrase "elicits an immune response against a pathogen, polypeptide, or anti-tumor antigen") overcome the rejection. This argument is not persuasive. This is because the claims still read on

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vaccines against the antigen sources identified in the claims. The inserted phrase merely illustrates that the claimed *vaccine* operates through the induction of an immune response, a mode of operation that was already implicitly in the claims through use of the term “vaccine.” However, the claims still read on vaccines where the Applicant has not demonstrated that the claimed compositions would be able to induce an effect prophylactic or therapeutic response against the indicated antigens.

9. **(Prior Rejection- Withdrawn)** Claims 39-41, 43, and 119 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims read on vaccines, and methods of making such, wherein the vaccines comprise an immunostimulant adsorbed onto a salt particle, and an antigen, but did not require that the metallic salt particle is substantially free of antigen. In view of the amendments to the claims, the rejection is withdrawn.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. **(Prior Rejection- Withdrawn)** Claims 71-81, and 104-114 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for failing to use proper Markush type language. In view of the amendments to the claims, the rejection is withdrawn.

12. **(Prior Rejection- Withdrawn)** Claims 71-81, and 104-114 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is withdrawn in view of the Applicant's arguments in traversal, which were persuasive.

13. **(Prior Rejection- Withdrawn)** Claims 71-81, and 104-114 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendments to the claims indicating that the antigens of the claimed inventions elicit an immune response against the indicated pathogens, rather than comprising the pathogens themselves, the rejection of the claims is withdrawn.

14. **(Prior Rejection- Withdrawn)** Claims 82-103 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendment of claims 71-81 such that they no longer require the antigen to comprise the whole of the target, pathogen, the rejection of claims 82-103 as lacking antecedent basis in the claims is withdrawn.

15. **(Prior Rejection- Withdrawn)** Claims 93-103 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is withdrawn in view of the Applicant's arguments in traversal, which were persuasive.

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16. **(Prior Rejection-Withdrawn)** Claim 43 was rejected under 35 U.S.C. 102(a) as being anticipated by Hauser et al., U.S. Patent 5,776,468. In view of the amendment of the claim such that it requires that the metallic salt to which the immunostimulant is adsorbed is substantially free of other antigen, the rejection is withdrawn.

Conclusion

17. Claims 82-92, 120-125 are objected to as depending from rejected claims.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


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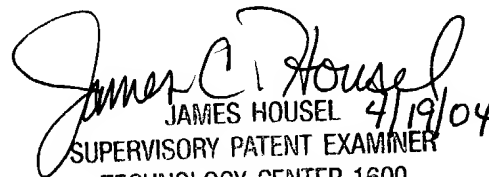
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


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